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May 26, 2020

VIA ECF

The Honorable Robert B. Kugler
United States District Judge
District of New Jersey

The Honorable Joel Schneider
United States Magistrate Judge
District of New Jersey

Re: In re Valsartan, Losartan, and Irbesartan Products Liability Litigation
Case No. 1:19-md-02875-RBK-JS

Dear Judge Kugler and Schneider:

This letter is to provide Defendants' positions with respect to the topics on the agenda for the conference with the Court on May 27.

1. Short Form Complaints

On February 19, 2020, the Court ordered certain Plaintiffs to file amended Short Form Complaints ("SFC") by March 3 to cure two types of deficiencies: (1) failure to properly serve the SFC through MDL Centrality, or (2) the over-identification of Defendants by checking every box on the form SFC. *See* Dkt. 377 ¶ 5. The Court later extended that deadline until March 23. *See* Dkt. 388 at 2. In light of the difficulties presented by COVID-19, the Defendants agreed to extend the deadline to cure deficient SFCs to May 20. A list of SFCs that remain deficient, all of which over-identify Defendants, is attached at **Exhibit A**. Defendants respectfully request the Court dismiss these deficient short form complaints for failure to comply with Rule 11.

2. Plaintiff Fact Sheets

Pursuant to Case Management Order No. 16 (Dkt. 249), Defendants submit the attached **Exhibit B** listing outstanding disputes between the parties with respect to Plaintiff's Fact Sheets ("PFS"). In accordance with the procedure established by the Court, Defendants reviewed the submitted Plaintiff's Fact Sheets in the listed cases and served deficiency letters on Plaintiff's counsel. The cases identified on Exhibit B are those where disputes were not resolved following receipt of a supplemental response or amended PFS.

To help facilitate resuming the show cause process, the parties met and conferred on May 11, 2020, at which time Defendants provided an exhibit with cases still in dispute as well as a list of issues they characterized as "core" deficiencies sufficient to render a PFS substantially incomplete. Plaintiffs requested that Defendants identify the sections of the personal injury PFS which corresponded to the list of core deficiencies and to amend their list of cases to focus on core deficiencies. Defendants provided Plaintiffs with a chart listing sections of the PFS which potentially contained core deficiencies on May 22, 2020, and noted that the prior exhibit list of cases would be updated to confine the identified deficiencies to "core" deficiencies wherever possible. (*See* **Exhibit C**, S. Harkins 5.22.2020 Email to M. Goldenberg). On Monday, May 25, 2020, Plaintiffs requested that the list of cases also be provided in advance of the May 27th Case Management Conference, (Ex. C, S. Harkins 5.22.2020 Email to M. Goldenberg), and Defendants sent the updated list to Plaintiffs on May 26, 2020. (Ex. C, email).

Defendants' Exhibit B contains lists of two sets of cases: those which are appearing on the list for the first time (Table A and Table B) and those which are appearing on the list for the second time (Table C). Under CMO 16, Defendants may request a show cause order be entered as to a delinquent party once it has appeared on the agenda for two Case Management Conferences ("CMC"). (*See* Dkt. 249). Accordingly, Defendants will continue to meet and confer and review supplemental responses and amended fact sheets as applicable for those cases identified on Table A and Table B, and no action by the Court on these cases is requested at this time. However, subject to the resolution of the discrete issues identified below, Defendants intend to request a show cause order returnable at the June 24, 2020 CMC with respect to those cases listed on Table C.

Defendants first discrete issue concerns the format of authorizations required by the PFS. The language the parties specifically negotiated requires: "For each primary health care provider, specialist used as a primary health care provider, and each health care provider who diagnosed or treated the injuries attributed to the Valsartan product, identified in the PFS, please provide a completed and signed (but undated) Health Care Authorization in the form attached as Exhibit 'A.'" (Dkt. 249, Ex. A). Plaintiff's counsel in numerous cases has taken the position that providing a single, blank Health Care Authorization form is sufficient. Defendants have encountered issues collecting records with such an authorization in other matters, and specifically negotiated for the above language with that in mind. Defendants request that the Court confirm authorizations are to be provided in the manner specified by the plain language of the PFS.

Second, Plaintiff's counsel in numerous cases have taken the position that they are not required to complete section III.G of the PFS which requires disclosure of medical expenses. (*See generally* Exhibit B). Alternatively, Plaintiff's counsel has in some instances represented that billing records produced in response to the PFS obviate the need to complete this section. Once again, this portion of the PFS was explicitly negotiated by the parties, and Defendants request that the Court confirm this section is to be completed by each responding Plaintiff, regardless of whether records with some cost information are also produced.

As the Court can see from the list of core deficiencies identified in Exhibit B, resolution of these issues should narrow the parties' disputes and limit the number of cases to be included on Defendants' request for a show cause order to be entered at the Jun 26, 2020 CMC.

3. ESI Search Terms

Pursuant to the Court's May 18, 2020 Order (Dkt. 432), and the Court's May 19, 2020 modification to that Order (Dkt. 434), Defendants will be filing their letter brief requesting modification of the search terms on May 27, 2020.

4. Manufacturer Defendant Fact Sheet

A. Introduction

By way of background, Plaintiffs propose four different Defendant Fact Sheets ("DFS") directed toward four distinct levels of the supply chain: Retailers, Wholesalers, Finished Dose Manufacturers, and API Manufacturers. Through these DFS, Plaintiffs hope to trace each valsartan tablet dispensed to a particular plaintiff upward through the supply chain, all the way to the specific lot of finished dose product and the specific batch of API. The idea is that the Retailers will first answer their DFS; the Wholesalers will then use that information to answer their DFS; and so on up the supply chain. *See* 1/15/20 Tr. at 28:21–29:1 ("[W]hen we take the information from the retailer going backwards up the distribution chain…now we know that James Smith took a pill with these identification numbers.").

As the Retailers and Wholesalers have explained to Plaintiffs and the Court, it is very unlikely that this endeavor will succeed. Neither the Retailers nor the Wholesalers track product based on lot number, and therefore there is, in most cases, no record showing which consumers received valsartan tablets from which finished dose lots. And to the extent product identification ***is*** provable on a granular, lot- or batch-specific basis, that proof would rest on speculation—***not*** on accurate, precise data that Defendants could provide through responses to a DFS. Although Plaintiffs would like to avoid the difficulty of connecting various data points that suggest a particular pill may have come from a particular lot or batch, that is the reality of product identification in the generic drug market. And that is Plaintiffs' burden to prove. *See, e.g., Namm v. Charles E. Frosst and Co., Inc.*, 427 A.2d 1121, 1125 (N.J. Super. 1981) ("It is a fundamental

principle of products liability law that a plaintiff must prove, as an essential element of his case, that the defendant manufacturer actually made the particular product which caused injury." (collecting cases)). Thus, although the Manufacturers have continued to negotiate the DFS, the Manufacturers have repeatedly cautioned that they likely cannot provide the granular, plaintiff-specific information that Plaintiffs seek.

The Manufacturers have agreed to a number of questions in the two DFS directed toward the API Manufacturers and the Finished Dose Manufacturers respectively (collectively, the "Manufacturer DFS"). Specifically, the Manufacturers have agreed to answer questions related to product identification, such as the identity of the manufacturer, lot or batch number, date of manufacture, expiration date, customer, and date of sale—to the extent it is possible to do so. *See* **Exhibits D and E** (attaching the Manufacturers' proposed DFS).[1] This is consistent with the Court's January ruling that the DFS shall include "product identification information," Dkt. 360 ¶ 5, but cannot otherwise duplicate the finalized Manufacturer document requests, *see* 1/28/20 Tr. at 64:4–5. Notwithstanding the Court's previous ruling, Plaintiffs insist that the DFS should go beyond product identification and further identify documents related to specific lots or batches, many of which have already been produced through core discovery and *all of which* will be produced in response to the Manufacturer document requests. Plaintiffs' position should be rejected as an attempt to relitigate the Court's earlier ruling and to impose on the Manufacturers unnecessary burden and expense.

B. Relevant Procedural History Related to Manufacturer DFS

After the Court finalized the Rule 34 document requests directed toward the Manufacturers, it became clear that the Manufacturer DFS requested information that was duplicative of the documents Plaintiffs would receive through document productions. For that reason, on January 15 the Manufacturer Defendants requested that the Court forego the DFS directed toward them entirely. *See* 1/14/20 Ltr. from S. Goldberg (Dkt. 338) at 8 (arguing DFS was now "unnecessary, cumulative, and unduly burdensome"). The Court agreed that "there can be no legitimate dispute that the fact sheets shouldn't duplicate what the…manufacturing defendants have to answer in the request for production," and asked the parties to "go back to the draft" DFS and "clean it up" in light of the scope of the document requests. 1/15/20 Tr. at 27:13–19. The Court instructed that the DFS should be limited to information "that's not covered by the document requests." *Id.* at 27:23–24.

Despite the Court's clear instructions, Plaintiffs proceeded to circulate two draft DFS directed toward the API and Finished Dose Manufacturers, respectively, that were almost ***entirely***

[1] The redlines in these exhibits represent the deletions or changes that the Manufacturers propose.

duplicative of the finalized document requests. *See* 1/27/20 Ltr. from S. Goldberg (Dkt. 353) at 25; *see also* Exhibit O to 1/27/20 Ltr. (Dkt. 353-15) (comparing DFS requests against Rule 34 requests). Plaintiffs argued that their proposed Manufacturer DFS were not duplicative of the Rule 34 document requests because they were designed to provide "product identification," or "what pills were taken by a particular plaintiff." 1/27/20 Ltr. from A. Slater (Dkt. 349) at 5; *see also* 1/28/20 Tr. at 83:15–18 (arguing that "specific product ID in a specific plaintiff's case" is not "duplication"). However, Plaintiffs' proposed DFS still contained questions that went well beyond identifying the particular tablets dispensed to an individual plaintiff. Defendants maintained that all questions, including product identification, were duplicative of the document requests.

Following the January 28 CMC, the Court adopted a middle ground and ordered that the Manufacturer DFS can contain questions "directed toward the product identification issue." Dkt. 360 ¶ 5. The Court also limited the DFS to "named class action plaintiffs and twenty (20) representative individual personal injury plaintiffs." *Id.* Beyond product identification information, the Court reiterated that the DFS cannot duplicate the Rule 34 requests. *See* 1/28/20 Tr. at 64:4–5 ("*No duplication*[.] [T]here can't be a dispute about that." (emphasis added)).

C. Summary of Recent Meet and Confers

Following the Court's January 30 ruling, the Manufacturer Defendants proposed versions of the DFS that would provide the information necessary to establish product ID—that is, NDC code, batch or lot number, date of manufacture, expiration date, customer, and date of sale, to the extent the Manufacturers are able to provide that information on a plaintiff-specific basis. The Manufacturer Defendants removed all questions that went beyond product identification except one question regarding communications with the individual plaintiff. In the last few weeks, the parties have exchanged multiple draft DFS and have met and conferred several times. However, the parties continue to dispute the appropriate scope of the DFS.

D. Argument

As explained below, the Manufacturer Defendants maintain that the DFS should be limited to product identification information, which will be a time consuming and burdensome process in and of itself. Once the Plaintiffs have product ID from the Manufacturers—such as lot and batch numbers, date of manufacture, expiration date, customer, and/or date of purchase—it should be Plaintiffs' burden to use that information to identify whatever other documents they believe are relevant to proving each individual case. The sections below address the broader reasons why the Court should reject each of the disputed DFS questions. In addition, the Manufacturers are prepared to address all disputed language at the May 27 CMC.

(i) The Court has already ruled that the DFS should be limited to product identification information.

In January, the Manufacturers requested that they no longer be required to respond to a DFS on the basis that all information requested, including documents showing product identification, would be equally discernible to Plaintiffs through the anticipated document productions. Plaintiffs argued that an expansive and burdensome DFS was still necessary to identify all documents that relate to a single plaintiff, not just the documents showing product ID. The Court adopted a middle ground, ordering that the Manufacturers must respond to a DFS, but that it will be limited to "product identification information." Dkt. 360 ¶ 5. Since that ruling, Plaintiffs have refused to remove most of their proposed questions that extend far beyond product ID. Their proposed Manufacturer DFS should therefore be rejected as an attempt to undermine the Court's earlier ruling.

(ii) Plaintiffs seek to avoid the burden of reviewing the expansive discovery they requested through Rule 34 document productions.

During meet and confers, Plaintiffs have insisted that the DFS go beyond product ID because they do not want to "look through a million pages" of documents to find those that relate to an individual case. *Cf.* 5/12/20 Ltr. from A. Slater (Dkt. 430) at 3 (explaining that DFS would allow Plaintiffs to avoid having to "identif[y]…the needles in the haystack that specifically apply to a particular Plaintiff"). If Plaintiffs did not want to undergo the burden and expense of reviewing millions of documents to find the ones relevant to their cases, they should not have requested such broad discovery to begin with. They should not be permitted to impose upon the Manufacturers the incredible expense of broad discovery—likely to exceed several millions of dollars per Manufacturer—only to turn around and also push the cost of reviewing those documents onto the Manufacturers.

Furthermore, when it suits them, Plaintiffs have repeatedly represented that they can review large volumes of documents. For example, when arguing for over 120 custodians from the ZHP entities alone, Plaintiffs represented that "lawyers in Benicar look[ed] at…[e]very single one" of the 64 million pages produced. 12/11/19 Tr. at 98:1–3. And when recently opposing the Manufacturers' proposed discovery extensions, Plaintiffs represented that they "have a large document review team" that "are ready to go." 4/15/20 Tr. at 9:24–10:2. This makes sense. To date, at least ***78 law firms*** either have filed personal injury actions or are members of Plaintiffs' Leadership. There is no reason that lawyers from these firms cannot review the discovery they have asked for to identify documents relevant to each of their cases. This is consistent with the Court's repeated statement that Plaintiffs must have "skin in the game" and do the work necessary to prove their cases. 7/24/19 Tr. at 8:18–21 (stating that one of the "themes run[ning] through the case" is that "Plaintiffs have skin in the game"); 7/10/19 Tr. at 22:9–19 (stating that "plaintiffs have skin in this game" and "have to do their homework").

(iii) Shifting the burden of identifying relevant documents to Defendants is not necessary to achieve Plaintiffs' stated goals of eliminating uncertainty and avoiding depositions.

Plaintiffs' second justification for the expansive DFS questions is similarly without merit. Plaintiffs have argued that the Manufacturers must identify documents relevant to particular plaintiffs because, otherwise, "there's a burden of uncertainty" about which documents relate to an individual case. 1/28/20 Tr. at 92:22–93:1. Plaintiffs have also argued that the only alternative to a burdensome DFS would be to rely on depositions of corporate representatives. *See id.* at 93:2–7. Neither point has value. Plaintiffs cannot circumvent discovery by having the Court mandate concessions by Defendants in the DFS to solidify Plaintiffs' claims. As in any case, Plaintiffs can identify the documents they believe are relevant to their own cases and then proceed with attempting to prove their cases thereon. That is the purpose of the Rule 34 document requests and productions.

(iv) Much of the information requested has already been produced through core discovery.

Several of the disputed questions should be rejected because they seek information that has already been produced through core discovery. For example, the two Manufacturer DFS request that the Manufacturers "identify and provide the results of all nitrosamine testing" performed on the relevant valsartan. Plaintiffs have already received documents showing the results of nitrosamine testing. For example, Prinston has produced documents identifying test results for all batches of ZHP's valsartan API and for all lots of finished dose valsartan that Solco has distributed in the United States. PRINSTON00080633 - PRINSTON00080685; PRINSTON00000191 - PRINSTON00000226; PRINSTON00000425 - PRINSTON00000453. Once Plaintiffs have product identification information—*i.e.*, the batch and lot number associated with a particular plaintiff—they are equally capable of reviewing these documents for the relevant test results. Questions regarding the scope of valsartan recalls should also be rejected on this basis, as the recall notices were produced in core discovery and are publicly available on the FDA website.

(v) All other information requested will be produced through Rule 34 discovery.

Similarly, many of the disputed questions should be rejected because they seek information that will be produced in response to the Manufacturer document requests. As shown above, the Court has repeatedly directed that the DFS cannot duplicate Rule 34 discovery. The burden of reviewing these documents should be on Plaintiffs, not on the Defendants. The table below identifies the DFS questions that fall in this category and their corresponding Rule 34 request.

DFS Request	Rule 34 Request
For each Affected API listed in response to Question II.A, identify whether any solvent used in the manufacture of these APIs was recycled or recovered, and if so, identify the recycled solvent, the entity(ies) that supplied the solvent, and on which date those solvents were used to manufacture the Affected API.	**Request No. 27:** Produce documentation identifying…the solvent(s) (including residual or reused solvents) utilized in the manufacture of each [lot or batch of valsartan]….
State whether you supplied each test result identified in response to Question II.B to the FDA or to any other entity or person (e.g., your actual or prospective customers) or Defendant, and, if so, identify the test result and provide the recipient of the test result, date of communication, and content of the communication.	**Request No. 10:** All communications between or among any of the defendants with regard to…testing capable of indicating purity, bioequivalence, or contamination, [or with regard to] quality assurance related to purity, bioequivalence, or contamination…. **Request No. 52:** Produce all regulatory documentation and communications with regard to contamination or recalls of valsartan, as limited by the Court's Order. **Request No. 80:** Produce all statements regarding purity, bioequivalence, and contamination provided to…direct and indirect purchasers of valsartan, for each NDC, Batch Number, and Lot Number of valsartan sold in the United States during the relevant time period.
Provide the date(s) on which you sent any recall notice that applied to any Affected API to any Defendants or pharmacies identified in the PFS, or any of your actual or prospective customers of the Affected API listed in response to Question II.A, and attach the recall notice(s).	**Request No. 69:** Produce all documents setting forth or addressing any communications with any customer or consumer relating to the recall (or nonrecall) of valsartan due to contamination. **Request No. 76:** Produce all communications (and drafts) to or from Defendant regarding recall of valsartan related to valsartan contamination, including lists sufficient to show all persons or entities who received communications.
Were any Affected API or Affected Drugs sold, distributed, labeled, or manufactured in whole or in	**Request No. 69:** Produce all documents setting forth or addressing any communications with

DFS Request	Rule 34 Request
part by you ever returned to your possession as a result of a recall letter, or finding or suspicion of contamination for allegedly or possibly containing a nitrosamine?	any customer or consumer relating to the recall (or nonrecall) of valsartan due to contamination.

(vi) The Manufacturers require 90 days to provide product identification information in response to each DFS.

The API and Finished Dose Manufacturers each require 90 days to respond to the DFS directed toward them. This time is necessary for three reasons: (1) because of the granular nature of the product identification information sought through the DFS, (2) because of the volume of information that would have to be reviewed for each plaintiff, and (3) because all of the DFS are likely to be due at the same time. The Court has ordered that product identification information must be provided for 54 plaintiffs (24 consumer class representatives, 10 medical monitoring class representatives, and 20 personal injury plaintiffs). *See* Dkt. 360 ¶ 5. Each of these plaintiffs alleges they were dispensed valsartan every 30 to 90 days over a period of years. One of the consumer class representatives, for example, has produced pharmacy records showing she was dispensed generic valsartan approximately ***55 times*** between 2012 and 2018. In other words, the Defendants would have to go through the burdensome—and likely impossible—process of searching through six years' of records to try to identify an untold number of lots and batches that were the source of her pills. That is an incredibly time consuming and burdensome process.

(vii) It is premature to require Manufacturers to identify an alternate cause of the Plaintiffs' alleged injuries.

Plaintiffs seek to have the Manufacturers identify an alternative cause for the alleged injuries through the DFS. It is currently premature to require Manufacturers to identify an alternative cause of the Plaintiffs' alleged injuries. At the very least, this question should state that no response is required until the deadline for exchanging expert reports, consistent with the DFS adopted in *Benicar*.

(viii) The Manufacturer Defendants should not have to search for communications with a specific Plaintiff unless that Plaintiff recalls communicating with the Manufacturer.

The Manufacturer Defendants have agreed to provide information regarding communications with individual Plaintiffs subject to two important limitations. First, the Manufacturers should be required to answer this question only for Plaintiffs who, in their Plaintiff Fact Sheets, indicate that they contacted the applicable Defendant. Plaintiffs are in a better position

to know whether they contacted a Manufacturer, and Manufacturers should not have to search through their records repeatedly when there is no reason to believe that a Plaintiff contacted them. Second, the responsive communications should be limited to official contact or communication channels. Otherwise, the Manufacturers would have to search through an unknown number of custodial and non-custodial records to determine whether any of their employees communicated with the individual plaintiffs during the many years that the plaintiff consumed valsartan. This limitation to communications through official contact centers is consistent with the language adopted in the *Benicar* DFS.

(ix) All requests for documents are duplicative of the finalized Rule 34 requests.

Plaintiffs also request that the Manufacturers produce documents in connection with responding to the DFS. These document requests are duplicative of the finalized Rule 34 requests directed toward the Manufacturers. The DFS requests documents related to the individual plaintiffs, communications with healthcare providers, and—for the Finished Dose Manufacturer DFS—documentation regarding transactional chargeback data. These topics are either duplicative of the finalized Rule 34 requests or are being handled through the discussions regarding production of sales and pricing information. *See, e.g.,* Request No. 69 (requesting communications with consumers regarding valsartan recalls); Request No. 80 (requesting communications with consumers regarding purity, bioequivalence, or contamination of valsartan); Request No. 86 (requesting communications with healthcare providers).

5. Core Discovery from Hetero Labs, Ltd., Hetero Drugs, Ltd., and Aurobindo Pharma, Ltd.

Defendant Hetero Labs, Ltd. ("HLL") and Plaintiffs have reached agreement on the following deadlines for producing the documents required by the Court's April 29, 2019 Order (Dkt. 88) ("Core Discovery Order"):

- By June 13, 2020, HLL will produce Establishment Inspection Reports, Form 483s, and correspondence with the FDA as required by the Core Discovery Order;
- By July 13, 2020, HLL will produce any outstanding Core Discovery items from 2013 onward not captured by previous productions;
- By July 31, 2020, HLL will produce any outstanding Core Discovery documents from 2011 to 2013.

Counsel for Defendant Aurobindo Pharma Ltd. ("Aurobindo") continues to engage in the meet-and-confer process with Plaintiffs' counsel on the deadline for core discovery. Plaintiffs proposed June 26, 2020 as the deadline. Aurobindo proposed July 31, 2020, and reserved the right to seek further guidance from the Court should that date become unworkable due to circumstances

relating to COVID-19, which continue to evolve. Plaintiffs proposed that Aurobindo produce certain FDA correspondence before July 31, 2020. Aurobindo anticipates the parties will reach an agreement on deadlines by May 27, 2020.

6. Manufacturer Sales & Pricing Productions

The Manufacturer Defendants have made productions of sales and pricing information that substantially comply with their obligation to respond to the single sales and pricing related document request in this litigation.

The final version of the Requests for Production of Documents to All API and Finished-Dose Manufacturing Defendants ("Manufacturer Document Requests"), which was adopted in the Court's December 23, 2019 Order (Dkt. 328), contains only one request for sales and pricing documents. *See* Dkt. 328 at 16. As reflected in the final set of Manufacturer Document Requests, ten additional requests had been withdrawn pursuant to a Court-approved agreement that was reached on the record during the December 11, 2019 Case Management Conference. *See id.* (showing requests 101-106 and 108-11 as withdrawn, leaving only request 107).

Under the Court's April 20, 2019 Text Order (Dkt. 416), each Manufacturer Defendant was required to make a production of its sales and pricing documents by May 15. Mylan made its production in accordance with an agreement resulting from its meet and confer efforts with Plaintiffs. ZHP (and its distributor Solco) also attempted to meet and confer with Plaintiffs, detailing by email on May 5 the documents that they were planning to produce. Plaintiffs did not respond to counsel for ZHP/Solco's email detailing their productions until May 14, the day before the document productions were due. Given that there was at that point no time to make adjustments and also abide by the May 15th deadline, ZHP and Solco made their sales and pricing productions on May 15th in accordance with their counsel's May 5th email. Plaintiffs did not attempt to meet and confer with the remaining Manufacturing Defendants prior to the May 15 production deadline.

On May 20 and 21, Plaintiffs sent letters to several Manufacturer Defendants, claiming that the Defendants' productions were deficient. Rather than focusing on purported failures to produce materials as agreed by the Parties to fulfill Document Request No. 107—the sole remaining sales and pricing request—these letters largely focused on complaints that Defendants had not produced certain information falling clearly outside that Request. For example, Plaintiffs demanded that the Manufacturer Defendants produce "data dictionaries or field keys." Not only does this information fall outside the scope of Document Request No. 107, but it requests information that was sought in one of the *withdrawn requests*. *Compare* **Exhibit F** at Document Request No. 111 with **Exhibit G** (Dkt. 328) at 16. Defendants certainly are not "deficient" for not producing information the request for which was explicitly withdrawn. Similarly, Plaintiffs complain that certain Defendants did not produce exemplar sets of documents that are sent to customers to correspond with each transaction (e.g., invoices, packing lists, etc.). Though these materials plainly fall outside the scope of Document Request No. 107, Mylan and ZHP produced these materials due to specific individual agreements with the Plaintiffs. Plaintiffs criticize some of the other Manufacturer Defendants for

not producing such documents, but this is clearly not a deficiency given that such documents fall outside Document Request No. 107 and Plaintiffs did not even request these materials from the other Manufacturer Defendants.

To the extent Plaintiffs have issues with the sales and pricing productions, the Stipulated Electronic Discovery Protocol entered in this case requires the parties to meet and confer. Case Management Order No. 8 (Dkt. 127) at 2. The Manufacturer Defendants are willing to engage in the meet and confer process on these issues. Indeed, counsel for ZHP/Solco initiated this process the day it received Plaintiffs' letter, and had a productive meet and confer with Plaintiffs on Friday, May 22, and Mylan has scheduled a meet and confer with Plaintiffs to be held during the afternoon of May 26.

7. Retailer/Wholesaler Macro Issues

Pursuant to the Court's May 18 Order (Dkt. 432), briefing on the Retailer Pharmacy and Wholesaler/Distributor Defendants' macro discovery issues is scheduled to be completed no later than June 22, with the Court to hear argument on these issues on June 24, 2020.

Last week, counsel for the Retail Pharmacy Defendants met and conferred with Plaintiffs regarding outstanding issues concerning those portions of Plaintiffs' draft Rule 34 request *not* impacted by the macro discovery briefing. Plaintiffs asked the Retail Pharmacy Defendants to confer and advise Plaintiffs when, approximately, the Retail Pharmacy Defendants could begin to produce documents for these requests. The Retail Pharmacy Defendants agreed to confer with their clients on an estimated production timeline once the remaining issues with these draft requests are resolved, but advised Plaintiffs that the production timeline may vary by defendant and, for some defendants, may continue to be impacted by challenges surrounding the current pandemic.

8. Prioritization of Manufacturer Productions

On May 7, 2020, Plaintiffs served a letter delineating various categories of documents that they would like prioritized in the Manufacturer Defendants' document productions. *See* **Exhibit H**. The Manufacturer Defendants responded by letter on May 22. *See* **Exhibit I**.

Consistent with the Court's instructions, the Manufacturers will make "reasonable, good faith efforts to comply with plaintiffs' prioritization." *See* MDL Text Order (Dkt. 416). Given differences in how each entity maintains its documents and the various states of accessibility of documents due to the current pandemic, there will be significant variability with respect to the information that each Manufacturer Defendant is able to prioritize for production. For this reason, the Manufacturer Defendants have requested individual meet and confers with Plaintiffs.

9. Plaintiffs' Leadership Structure

Defendants take no position regarding Plaintiffs' Motion to Expand Plaintiffs' Steering Committee.

Respectfully submitted,

/s/ Seth A. Goldberg

Seth A. Goldberg

cc: Adam Slater, Esq. (*via email*, *for distribution to Plaintiffs' Counsel*)
Jessica Priselac, Esq. (*via email*, *for distribution to Defendants' Counsel*)
Sarah Johnston, Esq. (*via email*)
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